UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,666	02/08/2002	Gyanendra Kumar	13172.0015U1	3290

7590 04/19/2004

NEEDLE & ROSENBERG, P.C.
Suite 1200
The Candler Building
127 Peachtree Street, N.E.
Atlanta, GA 30303-1811

EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,666	KUMAR ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-138* is/are pending in the application.

4a) Of the above claim(s) *137 and 138* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-136* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the office action and amendment filed on January 5, 2004 has been entered.

2. Claims 1-138 are pending Claims 137-138 are withdrawn.

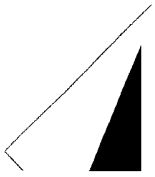
3. This application is filed on February 8, 2002.

Response to Arguments

4. Applicant's response to the office action is fully considered and is found persuasive in part.

5. With regard to the applicants' arguments on restriction requirement, applicants' arguments are fully considered and found persuasive in part. Applicants' arguments regarding the use of MPEP 825.02 are persuasive. Applicants correctly pointed out the error using the said paragraph and Examiner recognizes that the use of MPEP 825.02 was an error. However, with regard to the arguments on traversal of restriction requirement, Applicants arguments are fully considered and found not persuasive for the following reasons:

The traversal is on the ground(s) that examining both the groups would not be a serious burden, since search for art relating to one group would result in art relating to the other group. This is not found persuasive because of the following reasons: (i) search for one group not necessarily result in art related to another group (ii) separate classification search is prima facie evidence of burden, (iii) the issues are not the same with respect to 35 U.S.C. 112 and 35 U.S.C. 101 statutes, (iv) separate Art units would examine the two Groups under ordinary circumstances. Further, Claims in Group I are drawn to a method for detecting one or more analytes and the claims in Group II are drawn to a kit comprising reporter binding molecules, and capture agents. These two groups are patentably distinct as for as the subject matter is concerned, because Group I



invention is directed to a method for detection, and invention in Group II is directed to a kit composition. Additional, search is required not only for class 435, subclass 6 for Group I but also the patents in class 536, subclass 22.1 for Group II. Review of these additional searches is prima facie evidence of burden. Therefore the requirement is still deemed proper and made final.

6. With regard to the rejection made in the previous office action under 35 USC 112, second paragraph Applicants' arguments and amendment are fully considered and found persuasive. The rejection is withdrawn herein in view of the arguments.

7. With regard to the rejection made in the previous office action under 35 USC 102(e), Applicants' arguments have been fully considered and found not persuasive. Applicants argue that Kingsmore et al. reference does not teach decoupling step of the instant claims that is decoupling of amplification target circles from the reporter binding molecules prior to replication of the instant claims. These arguments are fully considered and found not persuasive because Kingsmore et al. does teach decoupling of amplification target circles from reporter binding molecules in example 7, on column 36, lines 21-27, wherein Kingsmore et al. disclose decoupling the circles from reporter binding molecules using capture agents (anti-antiboby IgE), and prior to replication of the circles. Additionally, Kingsmore et al. patent '283, on column 14, lines 25-50, disclose use of capture agents to capture analyte and to wash away reaction components that might interfere with subsequent steps. Further Kingsmore et al. also teach multiple separations or dissociation of analytes prior to or simultaneously with the each of the method steps (see and column 24, lines 36-38). Thus this clearly suggests separation is an alternate for decoupling.

Further, Kingsmore disclose that the method allows to produce tandem sequence DNA (see column 7, lines 62-67, column 8, lines 1-17). Thus the disclosure of Kingsmore et al. meets the limitations in the instant claims to address the limitations on decoupling the rejection is rewritten as follows:

Claims 1, 12-113, 118-136 are rejected under 35 U.S.C. 102(e) as being anticipated by Kingsmore et al. (USPN. 6,531,283).

With reference to the instant claims 1, 30, 43-49, 107, 124-126, 133-136, Kingsmore et al. teach a method for detecting one or more analytes comprising (a) bringing into contact one or more analyte samples and one or more reporter binding molecules (reporter primers), wherein each reporter binding molecule comprises a specific binding molecule and an amplification target circle, wherein each specific binding molecule interacts with an analyte directly or indirectly, incubating the analyte samples and the reporter binding molecules under conditions that promote interaction of the specific binding molecules and analytes (see column 41, lines 33-55); (b) decoupling or separating analytes using capture agents or separating analytes using capture agents after interaction of analyte samples with reporter binding molecules, thus separating analytes (see column 14, lines 25-50, column 2 and column 24, lines 36-38, column 42, lines 55-60, column 36, lines 21-24); (c) bringing into contact the amplification target circles and one or more rolling circle replication primer(s), wherein the amplification target circles each comprise a single-stranded, circular DNA molecule comprising a primer complement portion, wherein the primer complement portion is complementary to at least one of the rolling circle primers and incubating the rolling circle replication primers and amplification target circles and the rolling circle replication primers (see column 41, lines 56-67); (d) incubating the rolling

circle primers and amplification target circles under conditions that promote replication of the amplification target circles wherein replication of the amplification target circles results in the formation of presence of the corresponding analytes (see column 42, lines 32-39).

With reference to the instant claims 12-22, Kingsmore et al. teach that the method comprises circle linkers (capture docks), wherein circle linker comprises cleavable bond which could be a disulfide bond, heterobifunctional succinimide bond (sulfo-GMBS) maleimide bond, dihydroxy bond or amino linking group (reactive group) which can be cleavable by treatment with a reducing agent (see column 14, lines 25-67, column 15, lines 1-4, column 30, lines 4-10).

With reference to the instant claims 23-29, Kingsmore et al. also teach that the method comprises (i) plurality of reporter binding molecules are brought into contact with the one or more analyte samples (see column 42, lines 40-42); (ii) plurality of analyte samples are brought into contact with the one or more reporter binding molecules (see column 42, lines 43-45); (iii) at least one of the analyte samples comprise a protein or peptide, a lipid, glycolipid or proteoglycan (see column 42, lines 46-49); (iv) at least one of the analytes is from a human source and a non-human source (see column 42, lines 50-53); and none of the analytes are nucleic acids (see column 42, lines 54-55);

With reference to the instant claims 31-32, 35, Kingsmore et al. teach that the method comprises capture agent(s) and analyte(s) associated with a solid support and the solid support comprises different reaction chambers or predefined regions (see column 42, lines 61-67); the said solid support comprises acrylamide, agarose, cellulose, nitrocellulose, glass, polystyrene or polyamino acids (see column 43, lines 29-37);

With reference to the instant claims 36-42, Kingsmore et al. also disclose that the method comprises (i) bringing into contact at least one of the analyte samples with at least one accessory molecule affecting interaction of at least one of the analytes and at least one of the capture agents simultaneously with or following step (a) (see column 43, lines 39-48); (ii) at least one analyte and accessory molecule are associated with the solid support simultaneously with or following step(a) (see column 43, lines 49-55); (iii) the accessory molecule is a protein kinase, a protein phosphatase, an enzyme or a compound (see column 43, lines 56-58); (iv) interaction of accessory molecule of interest, with one or more analytes are test molecules of interest are detected (see column 43, lines 59-65);

With reference to the instant claims 43-75, Kingsmore et al. also teach that the method comprises (i) one or more first analyte samples and one or more second analyte samples, one or more first reporter binding molecules, one or more second reporter molecules, wherein each different reporter binding molecule is different and each different rolling circle primer primes replication of a different amplification target circle and produces a different tandem sequence DNA (see column 44, lines 9-43); (ii) the tandem sequence DNA corresponding to one of the analyte samples produced in association with an analyte capture agent is in the same location on the solid support as tandem sequence DNA corresponding to the same analyte and produced in association with the matching second analyte capture agent, wherein presence or absence of the same analyte in different analyte samples is indicated by the presence or absence of corresponding tandem sequence DNA (see column 44, lines 53-67, column 45, lines 1-5); (iii) at least one analyte and accessory molecule are associated with the solid support simultaneously with or following step(a) (see column 45, lines 6-55); (iii) the accessory molecule is a protein

kinase, a protein phosphatase, an enzyme or a compound (see column 45, lines 36-38); (iv) the accessory molecule is an analog and facilitates interaction of at least one of the analyte capture agents (see column 45, lines 27-35); accessory molecule is at least 20%, 50% , 80%, 90% pure and is associated with solid support (see column 45, lines 39-47);

With reference to the instant claims 76-83, Kingsmore et al. teach that the method comprises modified form of analyte wherein at least one or more analyte capture agents interacts directly or indirectly with the modified analyte, wherein the modification is post-translational modification, that is phosphorylation or glycosylation (see column 45, lines 55-65); detection of tandem sequence DNA is accompanied by mixing a set of detection probes under conditions to promote hybridization, wherein plurality of different tandem sequence DNAs are detected separately or simultaneously via multiplex detection (see column 45, lines 66-67, column 46, lines 1-7); detection probes are labeled using combinatorial multicolor coding (see column 46, lines 8-9); the method further comprises brining into contact a secondary DNA strand displacement primer and the tandem sequence DNA, and incubating under conditions that promote (i) hybridization between the tandem sequence DNA and the secondary DNA strand displacement primer, (ii) replication of the tandem sequence DNA (see column 46, lines 10-19);

With reference to the instant claims 85-106, 128-132, Kingsmore et al. teach that the method comprises detection labels as fluorescent moieties including fluorescent quenchers, which are incorporated into nucleic acids during amplification (see column 15, lines 55-67, column 16, lines 1-18).

With reference to the instant claims 108-112, Kingsmore et al. further teach that the method comprises (i) treating one or more analyte samples so that one or more samples modified

(see column 26, lines 15-48); bringing into contact one or more analytes and one or more arrays wherein each array comprises a set of analyte capture agents, a set of accessory molecules, each interacting directly or indirectly with an analyte, contacting one or more reporter binding molecules under conditions promoting interaction of the specific binding molecules analytes, analyte capture agents and accessory molecules, replicating with rolling circle replication primers to form tandem sequence DNA (see column 26, lines 50-67, column 27, lines 1-23); (ii) comprises solid support wherein components are immobilized to the solid support at a density exceeding 400 different components per cubic centimeter (see column 21, lines 8-19);

With reference to the instant claims 113-123, Kingsmore et al. also teach that the method comprises (i) analyte capture agents as peptides (see column 13, lines 59-66) immobilized on a solid support comprising 20% to 99% pure capture agents (see column 15, lines 5-20); (ii) comprises peptide, antibodies (antibodies are made up of short peptides) which comprise amino acids of about 20 amino acids (see column 13, lines 59-67, column 14, lines 1-11). Thus the disclosure of Kingsmore et al. meets the limitations in the instant claims.

8. With reference to the rejection made in the previous office action under 35 USC 103(a), Applicants' arguments are fully considered and found not persuasive. Applicants' argue Kingsmore et al. does not teach decoupling of ATC prior to replication and there is no suggestion or teaching to combine the teachings of Kingsmore et al. in view of Lizardi et al. As discussed above, Kingsmore et al. does disclose decoupling step. Further, in response to no suggestion or teaching to combine the teachings of Kingsmore et al. in view of Lizardi et al. examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching,

suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir.1992). In this case, specific motivation is provided by the teachings of Lizardi et al., which teaches efficiency of hybridization and coupling of detector probes to sample fragments can be improved by grouping detector probes of similar hybrid stability in sections or segments of a probe array that can be subjected to different hybridization conditions"(see column 13, lines 14-19). An ordinary practitioner would have been motivated to combine the method of detecting one or more analytes as taught by Kingsmore et al. with the inclusion of the limitations of hybridization probes as taught by Lizardi et al. in order to achieve the expected advantage of a rapid and sensitive method for detecting analyte(s) because inclusion of such limitations would enhance the sensitivity of the detection method. The rejection is rewritten as follows:

Claims 2-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kingsmore et al. (USPN. 6,531,283) and in view of Lizardi et al. (6,403,319).

Kingsmore et al. teach a method for detecting one or more analytes comprising (a) bringing into contact one or more analyte samples and one or more reporter binding molecules (reporter primers), wherein each reporter binding molecule comprises a specific binding molecule and an amplification target circle, wherein each specific binding molecule interacts with an analyte directly or indirectly, incubating the analyte samples and the reporter binding molecules under conditions that promote interaction of the specific binding molecules and analytes (see column 41, lines 33-55); (b) decoupling or separating analytes using capture agents or separating analytes using capture agents after interaction of analyte samples with reporter

binding molecules, thus separating analytes (see column 14, lines 25-50, column 2 and column 24, lines 36-38, column 42, lines 55-60, column 36, lines 21-24); (c) bringing into contact the amplification target circles and one or more rolling circle replication primer(s), wherein the amplification target circles each comprise a single-stranded, circular DNA molecule comprising a primer complement portion, wherein the primer complement portion is complementary to at least one of the rolling circle primers and incubating the rolling circle replication primers and amplification target circles and the rolling circle replication primers (see column 41, lines 56-67); (d) incubating the rolling circle primers and amplification target circles under conditions that promote replication of the amplification target circles wherein replication of the amplification target circles results in the formation of presence of the corresponding analytes (see column 42, lines 32-39). Kingsmore et al. further teach that reporter binding molecules further comprise capture probe (capture agents) (see column 42, lines 40-45). Kingsmore et al. also teach that the method comprises (i) analyte capture agents as peptides (see column 13, lines 59-66) immobilized on a solid support comprising 20% to 99% pure capture agents (see column 15, lines 5-20). However, Kingsmore et al. did not teach non-covalent interaction (base-pairing) of circle probe with reporter binding molecules and capture probe comprising oligonucleotide.

Lizardi et al. teach a method for analysis of sequence based coupling of the amplified fragments to detector probes wherein Lizardi et al. teach that the method comprises detector probes (oligonucleotides) having a free 5' end or a free 3'-end and a label (reporter) coupled to the probes bounded either covalently or non-covalently to the component (see column 11, lines 66-67, column 12, lines 1-10, column 14, lines 1-17). Lizardi et al. also teach incorporation of peptide molecules into the probes with varying mass labels (see column 38, lines 44-55).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of detecting one or more analytes as taught by Kingsmore et al. with the method as taught by Lizardi et al, to develop an enhanced method for the detection of analyte(s) because Lizardi et al. states that "efficiency of hybridization and coupling of detector probes to sample fragments can be improved by grouping detector probes of similar hybrid stability in sections or segments of a probe array that can be subjected to different hybridization conditions"(see column 13, lines 14-19). An ordinary practitioner would have been motivated to combine the method of detecting one or more analytes as taught by Kingsmore et al. with the inclusion of the limitations taught by Lizardi et al. in order to achieve the expected advantage of a rapid and sensitive method for detecting analyte(s) because inclusion of such limitations would enhance the sensitivity of the detection method.

9. With regard to the rejection made in the previous office action under obviousness type double-patenting, Applicants' arguments are fully considered and found not persuasive. Applicants argue that separation and decoupling are different and distinct processes and Kingsmore et al. does not disclose decoupling step. Applicants' arguments are fully considered and found not persuasive because, as discussed above Kingsmore et al. does disclose decoupling step as discussed above, wherein Kingsmore et al. patent '283, on column 14, lines 25-50, disclose use of capture agents to capture analyte and to wash away reaction components that might interfere with subsequent steps. Further Kingsmore et al. also teach multiple separations or dissociation of analytes prior to or simultaneously with the each of the method steps (see and column 24, lines 36-38). Thus this clearly suggests separation is an alternate for decoupling. Thus

decoupling step is an obvious variation and therefore the double-patenting rejection is maintained herein.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
April 5, 2004

JEFFREY FREDMAN
PRIMARY EXAMINER